UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LEON D. BOROCHOFF, on behalf of himself and all other similarly situated,	:	
Plaintiff,	:	CIVIL ACTION
v.	:	
GLAXOSMITHKLINE PLC, et al.,	:	NO. 07-CIV-5574 (LLS)
Defendants.	:	

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

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Defendants GlaxoSmithKline plc ("GSK" or "the Company"), Jean-Pierre Garnier, Ph.D., David Stout, Julian Heslop and Simon Bicknell ("Individual Defendants") (collectively "defendants"), by their attorneys, respectfully submit this memorandum of law in reply to plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Amended Complaint ("plaintiffs' Opposition Brief").

I. INTRODUCTION

As discussed at length in defendants' Opening Brief, the allegations of plaintiffs' Amended Complaint ("Complaint"), taken together with public documents properly considered by the Court, not only fail to support the Rule 10b-5 theory plaintiffs have attempted to stitch together but affirmatively contradict plaintiffs' claims of "fraud." Far from supporting plaintiffs' theory that defendants sought to withhold information as part of some deliberately deceptive scheme, the Complaint's allegations and public documents indisputably show instead that GSK voluntarily disclosed to the Food and Drug Administration ("FDA" or "Agency") the results of its Avandia "meta-analysis," which observed an increased risk for myocardial ischemia. The Company also provided the Agency with the results of an observational Balanced Cohort Study, which showed no such increased risk. Given the "important limitations" of a meta-analysis[1] and

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[1] As explained in defendants' Opening Brief, a meta-analysis attempts to extrapolate data from prior studies that were not specifically designed to test the hypothesis in question, many of which may be statistically insignificant and which frequently involve different protocols. (*See* Defs.' Opening Br. at n. 7, 9-10, Defs.' Exh. 15, von Eschenbach Statement at 15-16; *see also* Defs.' Exh. 37, Nissen Article at 2458-59 (describing Dr. Nissen's methodology)). Indeed, as FDA Commissioner von Eschenbach explained, GSK's final meta-analysis included 42 clinical trials which, in general, "had differing primary efficacy endpoints;" "were not designed to thoroughly investigate cardiovascular safety;" involved "varied" treatment groups with "rosiglitazone alone or in combination with insulin, sulfonylureas, and/or metformin;" involved "varied" comparator arms with "placebo alone or as an add-on treatment to other anti-diabetic agents, and other active anti-diabetic treatment regimens;" involved a combined patient population which "was diverse, including patients with average duration of diabetes ranging from 5 to 13 years as well as patients with significant risk factors for cardiovascular disease (e.g., history of myocardial infarction, bypass surgery, stroke, peripheral vascular disease, and New York Heart Association Class I and 2 heart failure); and, with the exception of four studies, "were six months in duration or less." (Defs.' Exh. 15, von

(continued...)

inconsistent data from the Balanced Cohort Study, the FDA did not issue a safety alert upon receipt of the meta-analysis data. Instead, the Agency decided to conduct further analyses of the data and also to await further information being developed through large, long-term clinical trials – a far more reliable basis for drawing scientific conclusions. In fact, the clinical trials confirmed the conclusions of the Balanced Cohort Study. The ADOPT and DREAM clinical trials (both published in peer reviewed journals in late 2006), as well as interim results from the long-term RECORD trial (released in June 2007), showed ***no*** statistically significant increased cardiovascular risk associated with the use of Avandia.

The fact that GSK posted its meta-analysis results on the Company's publicly available Clinical Trial Register ("CTR") in or about October 2006 further undermines plaintiffs' theory that defendants sought to conceal the data pursuant to an alleged fraudulent scheme. (*See* Defs.' Opening Br. at 20; Defs.' Exh. 45, Results from GSK Meta-Analysis and Balanced Cohort Study.) Indeed, Dr. Nissen himself utilized certain clinical trial data posted on GSK's CTR for his meta-analysis, and, in the process, reviewed GSK's meta-analysis and Balanced Cohort Study results that had been posted there. (*See* Defs.' Exh. 37, Nissen Article at 2458-59; Defs.' Exh. 38, Anna Wilde Mathews, *Medical Detective – Sequel for Vioxx Critic: Attack on Diabetes Pill: Glaxo Shares Plunge as Dr. Nissen Sees Risk to Heart from Avandia*, Wall St. J., May 22, 2007, at A1.)

Plaintiffs do not dispute these facts of public record. Instead, they contend that, because defendants knew of the meta-analysis results GSK submitted to the FDA, their failure to

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Eschenbach Statement at 8-9.) Accordingly, the FDA "has historically been cautious in the use of meta-analyses in support of regulatory decisions." (*Id.* at 15-16.)

mention those data to investors must have been the product of some fraudulent design. But this argument is founded on unsupported factual inferences and erroneous legal premises.

To begin with, plaintiffs' Opposition Brief pays scant attention to the fundamental element of scienter, despite the requirement that they plead facts sufficient to create a "strong inference" of scienter as to each and every defendant. For example, plaintiffs' attempt to demonstrate "strong circumstantial evidence of conscious behavior or recklessness" boils down to a single assertion: Defendants knew about GSK's meta-analysis results, *ergo*, they must have acted with scienter when they did not mention these data in their public statements. But plaintiffs' contention confuses the fact of non-disclosure with the quite different inquiry required for purposes of assessing scienter: Did defendants believe, or recklessly disregard, that disclosure was required and that nondisclosure would be misleading? Plaintiffs completely ignore the essential requirement that the defendant must have been aware that "non-disclosure would likely mislead investors." *City of Phila. v. Fleming Cos.*, 264 F.3d 1245, 1261 (10th Cir. 2001). Indeed, because the Complaint fails to present facts indicating a clear duty to disclose (*see infra* Section II.C), plaintiffs' allegation of a failure to disclose, alone, cannot support an inference of reckless conduct. *Kalnit v. Eichler*, 264 F.3d 131, 143-44 (2d Cir. 2001) (holding that, absent factual allegations showing a clear duty to disclose, "defendants' recklessness cannot be inferred from the failure to disclose").

Moreover, plaintiffs' Opposition Brief fails to identify *any* facts supporting an inference that defendants knew or believed at the time that what they said was in anyway misleading by virtue of some nondisclosure. To the contrary, the Complaint's allegations themselves suggest nothing more than that defendants (like the FDA itself) did not believe it necessary or scientifically appropriate to focus investors' attention on what they believed to be

inconclusive meta-analysis results contradicted by other, more reliable data. Even then, however, GSK disclosed the meta-analysis results to the FDA and made the data available on its publicly accessible CTR for interested persons to review -- actions patently inconsistent with some concerted effort to mislead through nondisclosure. Plaintiffs make virtually no effort to come to grips with these facts and the competing non-culpable inferences to which they give rise.

Plaintiffs' alternative attempt to create a "strong inference" of scienter through "motive" allegations fares no better. In their Opposition Brief, plaintiffs argue that the fact that *some* stock sales by GSK officers occurred during the extended class period alone is enough to create a "strong inference" of scienter. But this contention ignores the large body of contrary case law, which makes clear that the mere fact of some sales is insufficient. Instead, a complaint must present a context that shows sales ***by defendants*** to be unusual and "suspicious." Not only have plaintiffs made no attempt to satisfy this requirement, but the full context regarding defendants' stock holdings and history (provided in defendants' Opening Brief), including the fact that two of the individual defendants had no sales of GSK stock at all and the other two *increased* their holdings during the putative Class Period, demonstrates that these sales were neither unusual nor suspicious.

Like their scienter allegations, plaintiffs' "duty to disclose" averments are fatally flawed. Misconstruing *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153 (2d Cir. 1998) ("*Carter-Wallace I*"), and its progeny, plaintiffs attempt to portray *Carter-Wallace I* as establishing a duty to disclose standard based only on "statistical significance." In plaintiffs' view, whenever a pharmaceutical company says anything about one of its products, it must simultaneously disclose any arguably adverse analysis or study that reaches the mathematical level of such "statistical significance." (Pls.' Opp'n Br. at 3, 15.) But plaintiffs' erroneous

interpretation of *Carter-Wallace I* would result in a wholly unworkable disclosure standard, and a dangerous one, because it ignores all of the other factors that go into evaluations about the scientific significance of studies. *Carter-Wallace I* mentioned statistical significance, not because it is the only relevant factor, but because it was the particular issue in that case. Indeed, the decision makes clear that a duty to disclose does not attach unless and until there is sufficiently reliable scientific evidence of a causal connection between a product and the alleged "ill effects" and such ill effects "are sufficiently serious and frequent to affect future earnings." *Carter-Wallace I*, 150 F.3d at 157. That is, and should be, the relevant threshold. Otherwise, under plaintiffs' interpretation of *Carter-Wallace I*, pharmaceutical companies would be required to inundate the public with any and all scientific and medical information that is considered "statistically significant" when viewed in isolation, regardless of whether such information, particularly when viewed in its scientific or medical context, is inconclusive or unreliable. (Defs.' Opening Br. at 35-36.)

Not only do plaintiffs try to mask their Complaint's failure to plead a duty to disclose by misconstruing the holding and import of *Carter-Wallace I*, but they also misstate and ignore facts presented in the Complaint and the public documents properly before the Court. For example, plaintiffs' Opposition Brief asserts that GSK's meta-analysis results "concluded that there was a statistically significant link between use of Avandia and the risk of heart attack." (Pls.' Opp'n Br. at 15.) In fact, the meta-analysis results did ***not*** show a "statistically significant link between the use of Avandia and the risk of heart attack;" nor does the Complaint allege any such connection. What the data did suggest was an increased risk for myocardial ***ischemia*** (insufficient blood flow to the heart) – not myocardial ***infarction*** (heart attack). (*See, e.g.*, Defs.' Opening Br. at 3 n.6, 16-18; Defs.' Exh. 15, von Eschenbach Statement at 9; Defs.' Exh. 16,

FDA Adv. Comm. Brief at 1; Defs.' Exh. 17, FDA Adv. Comm. Intro. Mem. at 3-4; Defs.' Exh. 45, Results from GSK Meta-Analysis and Balanced Cohort Study.) Plaintiffs also ignore – in both their Complaint and their Opposition Brief – the existence of the Balance Cohort Study data, which, along with the results from the ADOPT, DREAM and RECORD clinical trials, conflicted with, and rendered inconclusive, GSK's meta-analysis data. (*See, e.g.*, Defs.' Opening Br. at 19-25; Defs.' Exh. 15, von Eschenbach Statement at 11.) An accurate reading of *Carter-Wallace I* and the facts before the Court, however, irrefutably shows that plaintiffs' Complaint fails to plead a duty to disclose.

For these reasons, and the others discussed below, the Complaint should be dismissed. Moreover, the dismissal should be with prejudice. Indeed, while plaintiffs seek leave to amend, they have already raised (and argued) on this motion to dismiss the other material they claim they would add via amendment – and none of it is sufficient to produce a different result.

II. ARGUMENT

A. Plaintiffs Misstate The Applicable Pleading Standards

As a threshold matter, plaintiffs' Opposition Brief misstates the applicable pleading standards. First, plaintiffs rely on decisions that not only have no applicability to the securities context – where heightened pleading standards are enforced – but do not even accurately reflect the current standards applied to notice pleading. All of plaintiffs' cases are based on the standard of *Conley v. Gibson*, 355 U.S. 41 (1957), but that standard was expressly abandoned by the Supreme Court in *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). (*See* Pls.' Opp'n Br. at 11-12 (citing *Scheuer v. Rhodes,* 416 U.S. 232, 236 (1974) (quoting *Conley*); *Caiola v. Citibank, N.A.*, 295 F.3d 312, 321 (2d Cir. 2002); *Ganino v. Citizens*

Utils. Co., 228 F.3d 154, 161 (2d Cir. 2000) (applying *Conley* standard); *In re Mercator Software, Inc.*, 161 F. Supp. 2d 143, 147 (D. Conn. 2001) (same)).[2]

Second, plaintiffs distort the pleading standard for scienter required under *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007). While they are correct that the Supreme Court stated in *Tellabs* that "[t]he inference that the defendant acted with scienter need not be irrefutable . . . or even the 'most plausible of competing inferences,'" *id.* 2510 (*see* Pls.' Opp'n Br. at 18), they ignore the remainder of that paragraph, which sets forth the holding of the *Tellabs*' decision:

> Yet the inference of scienter must be ***more than*** merely "reasonable" or "permissible" – it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.

Id. (emphasis added).

Moreover, plaintiffs misleadingly ***omit*** the following highlighted text from their purported recitation of the Supreme Court's "prescriptions" for determining whether a complaint meets the PSLRA's heightened pleading standards:

> [C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, ***in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice***.

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[2] None of the cases cited by plaintiffs supports their assertion that, "[i]n reviewing a motion to dismiss, the Court must . . . give Plaintiffs the benefit of ***every favorable*** inference that can be drawn from its allegations." (Pls.' Opp'n Br. at 11 (emphasis added).) To the contrary, *Twombly*, cited on page 12 of plaintiffs' Opposition Brief, requires that a claim for relief be "plausible on its face." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). Therefore, when deciding a motion to dismiss, a court must consider ***only*** those factual allegations that "raise a right to relief above the speculative level." *Id.* at 1965. In short, it is only "reasonable" inferences that are drawn in plaintiffs' favor.

Id. at 2509 (emphasis added). Indeed, as defendants have explained (Defs.' Opening Br. at 7 n.13, 30): "'The Court need not accept as true any allegations that are contradicted by documents deemed to be part of the complaint, or materials amenable to judicial notice.'" *In re Yukos Oil Co. Sec. Litig.*, No. 04-CV-5243, 2006 WL 3026024, at *12 (S.D.N.Y. Oct. 25, 2006).[3] Accordingly, the Court need not accept as true plaintiffs' factual allegations to the extent they are inconsistent with or contradict documents incorporated in the Complaint by reference or matters of which a court may take judicial notice.[4]

B. Plaintiffs' Opposition Brief Fails To Address The Fatal Deficiencies Of The Complaint's Scienter Allegations

As noted above, plaintiffs' Opposition Brief gives short shrift to defendants' argument that the Complaint fails to adequately plead scienter. Because plaintiffs pay so little attention to their deficient scienter allegations, and because their failure to adequately allege scienter is alone fatal to the Complaint, we begin by addressing this fundamental flaw.

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[3] *Accord In re Aegon N.V. Sec. Litig.*, No. 03-CV-0603, 2004 WL 1415973, at *5 (S.D.N.Y. June 23, 2004); *In re Bayer AG Sec. Litig.*, No. 03-Civ-1546, 2004 WL 2190357, at *11 (S.D.N.Y. Sept. 30, 2004); *Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000); *In re Hunter Envtl. Servs. Inc. Sec. Litig.*, 921 F. Supp. 914, 918-19 (D. Conn. 1996).

[4] Plaintiffs also assert that defendants have mischaracterized the PSLRA pleading standard by stating that the court need only accept as true non-conclusory factual allegations based on personal knowledge; they claim that *Tellabs* says no such thing. (Pls.' Opp'n Br. at 19.) While the issue is of no moment to disposition of the current motion, plaintiffs' observation is irrelevant because the standard in this regard does not derive from *Tellabs*. Rather, it is expressly set forth in the text of the PSLRA itself, which requires that if a complaint makes allegations based on information and belief, as opposed to personal knowledge, "the complaint ***shall*** state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1) (emphasis added). Thus, for allegations not based on personal knowledge, mere assertions are not sufficient; rather, the facts supporting those allegations must also be alleged so as to allow an assessment of whether they adequately support the "information and belief" allegation.

1. Plaintiffs Have Failed To Plead Facts Showing That The Meta-Analysis Information Was So Obviously Material That Defendants Must Have Been Aware Both Of Its Materiality And That Its Non-Disclosure Would Likely Mislead Investors

Plaintiffs contend that the following averments are sufficient to establish recklessness for purposes of pleading a strong inference of scienter: (1) defendants knew that the meta-analysis results existed; and (2) defendants did not disclose the data to investors. (*See, e.g.*, Pls.' Opp'n Br. at 20.) As defendants have explained (Defs.' Opening Br. at 43-44), however, the relevant inquiry for pleading recklessness under the PSLRA is "not merely whether [the defendant] had knowledge of the undisclosed facts; rather, it is the *danger of misleading buyers* that must be actually known or so obvious that any reasonable man would be legally bound as knowing." *City of Phila. v. Fleming Cos.*, 264 F.3d 1245, 1260-61 (10th Cir. 2001) (citing *Schlifke v. Seafirst Corp.*, 866 F.2d 935, 946 (7th Cir. 1989)) (emphasis in original).[5] Moreover, an inference of scienter from the mere fact of nondisclosure is especially inappropriate where, as here, the underlying alleged duty to disclose is itself not "clear," *i.e.*, unambiguous and free from doubt, but occupies what is at best a gray area (*see infra* Section II.C). *See, e.g.*, *Kalnit v. Eichler*, 264 F.3d 131, 144 (2d Cir. 2001) ("Because . . . this case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide ***strong*** evidence of conscious misbehavior or recklessness.") (emphasis in original).

Neither the Complaint nor plaintiffs' Opposition Brief points to any facts showing that defendants were aware that the non-disclosure of the meta-analyses to investors "would

[5] *Accord CP St. Louis Casino LLC v. Casino Queen Inc.*, No. 07-CV-447, 2007 WL 3119828, at *5 (S.D. Ill. Oct. 23, 2007); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *14 (E.D. Pa. Nov. 1, 2006); *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 638-39 (D.N.J. 2002). Plaintiffs do not dispute the applicability of this standard; nor do they take issue with any of the authority cited by defendants.

likely mislead investors."[6] *Fleming*, 264 F.3d at 1261. Plaintiffs have not presented a single well-pleaded fact – by way of contemporaneous internal documents, confidential sources, or otherwise – that in any way suggests that defendants were aware that their statements during the Class Period were misleading or that they were under an obligation to further disclose meta-analysis results that were, at best, inconclusive and uncertain. Nor do plaintiffs make any attempt to grapple with the competing inferences of non-culpability that must be considered under *Tellabs*. For instance, plaintiffs do not even try to explain, much less point to any pleaded facts, as to why GSK would voluntarily disclose the meta-analyses to the FDA if the defendants were engaged in some scheme to deceive the public. That conduct is far more consistent with an inference of innocence than an inference of an intent to defraud. Similarly, the fact that, while in possession of GSK's meta-analysis data, the FDA itself had not determined the data's clinical significance and did not require GSK to change its practices or alter its disclosures, underscores the more plausible inference that defendants believed they were under no obligation to make further disclosures.

In addition, not only did GSK disclose the meta-analysis results to the FDA, but it also posted the data on its CTR (which is accessible through the Company's website), further undermining any inference of an intent to conceal information from the public. Plaintiffs try to minimize the significance of this fact by saying that the data was indecipherable. (Pls' Opp'n Br. at 23.) But plaintiffs identify no pleaded factual allegations in support of this bare assertion. In any event, whether scientific data is indecipherable to a lay person is beside the point. The

[6] Plaintiffs' "core products" argument (Pls.' Opp'n Br. at 21-22) is also irrelevant here and misses the salient issue. The issue is not whether defendants were aware of the meta-analysis results – which is at best what "core products" presumptions concern – but whether defendants were aware that the meta-analysis should have been the subject of some additional disclosures to investors.

critical fact about GSK's posting the data on its website is that the data then became available for interested persons to review and analyze, which is hardly consistent with an intent to deceive. In fact, while gleaning clinical trial data from GSK's CTR for his meta-analysis of Avandia, Dr. Nissen observed that the Company had posted its own meta-analysis data on the CTR. (*See, e.g.*, Defs.' Opening Br. at 22.) Put simply, nothing about defendants' conduct bespeaks any intent to defraud. To the contrary, defendants' conduct was far more consistent with a belief that GSK was not required to make any further disclosure, and that to do so would have been inappropriate, particularly in the face of conflicting data from more rigorous studies.

Plaintiffs' assertion that "the Individual Defendants were high-level executives who had access to undisclosed information regarding Avandia, and thus *knew that Glaxo's business would suffer when the public learned of the direct association between Avandia and its link to increased risk of heart attack*" (Pls' Opp'n. Br. at 21 (emphasis added)), merely underscores the insufficiency of plaintiffs' scienter allegations. Not surprisingly, plaintiffs provide no citation for this mere rhetorical assertion regarding what the Individual Defendants supposedly "knew." That is because the Complaint contains no allegations even remotely suggesting that any Individual Defendant held any such belief. Nor is there any basis for an inference that any Individual Defendant himself believed, when considering the totality of the information available, that the meta-analysis constituted meaningful evidence of a link between Avandia and increased risk of heart attacks, much less was "sufficiently serious to affect future earnings." In this respect, the facts here stand in stark contrast to those of *Bayer*, which involved detailed factual allegations that the company had reached an internal consensus regarding a threat to the future viability of its product at a particular meeting. *In re Bayer AG Sec. Litig.*, No. 03-Civ-1546, 2004 WL 2190357, at **5, 8-9 (S.D.N.Y. Sept. 30, 2004). Thus, the only cogent

and compelling inference to be drawn here is that the defendants had no intent to defraud investors.

Plaintiffs try to refute this compelling inference by quoting a statement made by Individual Defendant Dr. Jean-Pierre Garnier in a July 9, 2007 *Wall Street Journal* article, seven weeks after the FDA issued its safety alert on May 21, 2007. (Pls.' Opp'n Br. at 5-6 (citing Defs.' Exh. 42, Whalen article); *see also* Compl. ¶ 35; Defs.' Opening Br. at 18-19.) Specifically, plaintiffs assert that Dr. Garnier's statement "We're not perfect, I'm sure. With 20-20 hindsight we could have done more" in response to the question "Has Glaxo done everything it could to study Avandia and communicate its risks to the public?" supports an inference of scienter. (Pls.' Opp'n Br. at 6, 22.) But plaintiffs have wrenched Dr. Garnier's comments from their context and in doing so have fundamentally mischaracterized his point. In pertinent part, the article states:

> Dr. Garnier is now trying to fight research with research. He says Glaxo performed its own meta-analysis of Avandia before Dr. Nissen's -- and also found a risk of heart attack. ***But the risk was very slight, and was outweighed by other evidence showing that Avandia is as safe for the heart as other diabetes drugs***, Dr. Garnier says. The Food and Drug Administration is now carrying out its own meta-analysis and will convene a panel of medical advisers on July 30 to weigh the evidence.

(Defs.' Exh. 42, Whalen article at B1 (emphasis added).) The article goes on to quote the following question and answer between the reporter and Dr. Garnier:

> **WSJ:** Has Glaxo done everything it could to study Avandia and communicate its risks to the public?
>
> **Dr. Garnier:** We're not perfect, I'm sure. With 20-20 hindsight we could have done more. But I have to say in the case of Avandia, you see that we were diligent from the day of the launch to start to study the drug in some depth in [clinical] studies and then we did the meta-analysis a year ahead of Dr. Nissen.

> ***As soon as we found out that there was at least a question raised by the meta-analysis, we immediately did the epidemiology study with 30,000 patients that came out absolutely squeaky clean and supportive of Avandia. So you look at the totality, Avandia is by far the most studied diabetic agent on the market today. So sure, maybe we could do more, but frankly the record is very good. Not only have we studied this drug right, left and center, but also we have been transparent, informed everybody.***

(*Id.* (emphasis added).) Thus, rather than support an inference of scienter, as plaintiffs argue, these statements by Dr. Garnier actually support the more compelling inference that he and the other defendants did ***not*** believe the meta-analysis information "was so obviously material that [they] must have been aware both of its materiality and that its non-disclosure would likely mislead investors." *Fleming*, 264 F.3d at 1261.

Finally, plaintiffs' new contention that GSK's interactions in 1999-2000 with Dr. John Buse somehow support a strong inference of scienter with regard to a meta-analysis *which did not even exist until many years later* is baseless. (*See* Pls.' Opp'n Br. at 1, 8-10.) The alleged interactions between the Company and Dr. Buse occurred well over five years before the events giving rise to this action – including even the existence of preliminary results of the meta-analyses at issue in this dispute – and cannot support any plausible inference of scienter as to its nondisclosure, let alone a strong one.[7] *See, e.g., Hart v. Internet Wire, Inc.*, 145 F. Supp. 2d 360, 368 (S.D.N.Y. 2001) (recognizing that "to withstand a motion to dismiss plaintiffs must detail specific ***contemporaneous*** data or information known to the defendants that was inconsistent with the representation in question") (emphasis added) (internal quotation marks and citation omitted); *accord In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 633 (S.D.N.Y. 2005)

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[7] The interactions concerned Dr. Buse's admitted speculation – not conclusions – at the time, in the absence of any studies, that there "may" be a connection between Avandia and cardiovascular risks. (*See* Pls'. Exh. A, at 2-4.) And while the interactions reflect GSK's disagreement with what it viewed to be that unfounded speculation, they do not remotely constitute an acknowledgment by GSK that any such risk actually existed.

(noting plaintiffs' failure to plead specific allegations of "***contemporaneous*** institutional knowledge") (emphasis added); *see also In re The Goodyear Tire & Rubber Co. Sec. Litig.*, 436 F. Supp. 873, 894 (N.D. Ohio 2006) (rejecting scienter averments based on alleged conduct that occurred before class period). Moreover, the PSLRA itself dictates that the scienter inquiry be one that is separately undertaken as to each alleged violation, *i.e.*, requiring as to "***each*** act or omission" facts giving rise to a "strong inference." 15 U.S.C. § 78u-4(b)(2) (emphasis supplied).

In short, the averments in the Complaint, the documents incorporated in the Complaint, and the matters of which the Court may take judicial notice provide no basis for any inference of an intent to defraud, much less a cogent and compelling one. While one can undoubtedly attempt (with hindsight) to second-guess GSK's judgment in not deeming the meta-analysis results significant or reliable enough (particularly in light of other contrary data, and the FDA's own reactions) to be disclosed beyond the FDA and the Company's CTR, this is simply not the stuff of fraud or conscious wrongdoing.

2. Plaintiffs' Opposition Brief Does Not Refute The Judicial Authority That Has Flatly Rejected The Type Of Stock Sales Plaintiffs Claim Support Their Motive And Opportunity Allegations

In apparent recognition of the futility of their position, plaintiffs' Opposition Brief presents scant argument in support of their "motive and opportunity" allegations. (*See* Pls.' Opp'n Br. at 23-26.) Unable to criticize or distinguish the cases cited in defendants' Opening Brief, plaintiffs simply ignore the applicable authority. They also disregard what is and is not actually pleaded in their Complaint.

First, as defendants previously pointed out, the Complaint does not plead any stock sales at all by two of the four defendants. (*See* Defs.' Opening Br. at 48.) That fact alone undermines any inference of scienter because those two defendants are not alleged to have had

any motive to engage in a scheme to defraud. *See, e.g., In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 75 (2d Cir. 2001) (discussing the court's decisions in *San Leandro* and *Acito* and noting that "in each case the failure of other defendants to sell their stock undermined the plaintiffs' theories that negative information was withheld to obtain a higher sell price"); *see also* Defs.' Opening Br. at 48-50. Plaintiffs do not even bother to address this deficiency in their Opposition Brief.

Second, while plaintiffs trumpet a figure of $27.5 million in stock sales (*see* Pls.' Opp'n Br. at 24; Compl. ¶ 70), they continue to turn a blind eye to the fact that the vast majority of those sales were made by individuals other than the Individual Defendants. (Defs.' Opening Br. at 50.) Indeed, the only two Individual Defendants who sold stock had sale proceeds of less than $6.5 million over the entire putative Class Period. (*Id.* at 51.) The remaining $21 million in stock sales by non-defendants simply have no bearing on defendants' state of mind. (*See* Defs.' Opening Br. at 48-51 & n.53.) The Second Circuit reached precisely this conclusion in the *Scholastic* case on which plaintiffs themselves rely:

> The second amended complaint in the present case . . . names only Marchuk as an individual defendant. ***Consequently, whether other [non-defendant] Scholastic officials sold their stock prior to the February 20, 1997 press release is not only unknown, but, as to Marchuk's possible liability, is also irrelevant, since in that regard motive is considered with respect to Marchuk alone.***

Scholastic, 252 F.3d at 75 (emphasis added).[8] The same is true here. Plaintiffs essentially concede as much by failing to address the issue.

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[8] Nor did the courts in any of the other cases cited by plaintiffs consider non-defendant insider stock sales as relevant to a defendant's state of mind. *See Rubinstein v. Collins*, 20 F.3d 160, 169 (5th Cir. 1994) (discussing only defendants' stock sales); *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474 (S.D.N.Y. 2004) (no insider trading allegations); *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 372 (S.D.N.Y. 2004) (discussing only defendants' stock sales); *In re Microstrategy, Inc. Sec. Litig.*, 115 F. Sup. 2d 620, 644-45 (E.D. Va. 2000) (discussing only defendants' stock sales); *In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 139-40 (S.D.N.Y. 1999) (discussing only defendants' stock sales); *In re MTC Elec. Tech. S'holders Litig.*, 898 (continued...)

Plaintiffs' assertion that "$13 million of the overall sales alleged in the [Complaint] took place just prior to the close of the Class Period" (Pls.' Opp'n Br. at 24), is similarly unavailing. The most recent sales listed in the Complaint are from February 2007, roughly three months before the close of the Class Period, not "just prior" to it, as plaintiffs assert. (Compl. ¶ 70.) And, like the $27.5 million plaintiffs cling to, the vast majority of those February sales are attributable to non-defendants and thus of no moment. (*Id.*)

Third, as to defendants Garnier and Stout, plaintiffs make no attempt to respond to the case law cited by defendants that requires allegations that stock sales were unusual in amount or timing. (*See* Defs.' Opening Br. at 51-55.)[9] Instead, relying almost exclusively on the district court's dicta in *In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133 (S.D.N.Y. 1999), plaintiffs attempt to claim that the mere fact of any significant sale, regardless of the context or other circumstances relating to that sale, is by itself sufficient to give rise to a strong inference of scienter. (Pls.' Opp'n Br. at 24-25 & n.27.) That has never been the rule in the Second Circuit.[10] Moreover, no such rule could survive *Tellabs* because *Tellabs* expressly requires consideration

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(continued...)

F. Supp. 974, 980 n. 4 (E.D.N.Y. 1995) (discussing only defendant's stock sales). Moreover, *Rubinstein* and *MTC Electronic* provide limited, if any, value to the scienter analysis, as neither was decided under the PSLRA.

[9] Even cases cited by plaintiffs recognize that, to survive a motion to dismiss, a plaintiff must plead some factual "context" to support a finding of unusual or suspicious trading (*i.e.*, trading outside the norm for a particular defendant). *See Scholastic*, 252 F.3d at 75 ("[The] dollar amount [of an insider's sales] cannot be considered in isolation."); *Microstrategy*, 115 F. Supp. 2d at 644 ("[T]he determination of whether insider sales were 'suspicious' is highly context-specific . . . ."); *see also* Defs.' Opening Br. at 51-55.

[10] *See In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 445 (S.D.N.Y. 2005) ("Plaintiffs' allegation that the insider sales resulted in more than $60 million in gross proceeds does not save the day. The significance of insider transactions in the scienter analysis is what, if anything, they suggest about the likely intent of the insiders. The gross proceeds, standing alone, tell us very little."); *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 382-83 (E.D.N.Y. 2003) (finding that plaintiffs failed to plead scienter despite allegations of $58 million in insider sales: "[P]laintiffs do not adequately plead that defendants, individually or collectively, sold a large percentage of their total shares; large dollar amounts, standing alone, typically do not suffice to establish motive.").

of *competing* inferences, which necessarily involves examination of contextuality. That is precisely why it is significant that the stock holdings of both defendants Garnier and Stout *increased* during the Class Period and that their sale transactions coincided with the nearly simultaneous exercise of expiring stock options. (Defs.' Opening Br. at 53-54.) When viewed in this context, as they must be under *Tellabs*, the stock sales of defendants Garnier and Stout support inferences that are far more consistent with innocent trading practices than with an intent to defraud.[11]

Because the Complaint is devoid of facts giving rise to a "strong" inference that defendants acted with scienter and intended to defraud investors, it should be dismissed.

C. Plaintiffs' "Duty To Disclose" Theory Is Erroneous

The Complaint must be dismissed for the additional reason that defendants simply had no duty under Section 10(b) to disclose the results of GSK's meta-analyses. (*See* Defs.' Opening Br. at 35-42.) As defendants' Opening Brief explained, *Carter-Wallace I* and its progeny require disclosure of safety risks where a pharmaceutical company has reason to believe – based on reliable scientific data – that the future viability of a product is in jeopardy. (Defs.' Opening Br. at 35-38.) Plaintiffs attempt to distort this standard by claiming that *Carter-Wallace* was based solely on the fact that the adverse event reports at issue there "did not provide a 'statistically significant' link between felbatol and the 'ill effects.'" (Pls.' Opp'n Br. at 15.)

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[11] Plaintiffs are incorrect when they suggest that, by challenging the adequacy of plaintiffs' "motive" pleading, defendants have raised matters beyond the scope of a motion to dismiss. (*See* Pls.' Opp'n Br. at 25 n.27.) As a threshold matter, defendants' primary contention is that plaintiffs' scienter allegations, ***on their face***, are inadequate as a matter of law. (*See* Defs.' Opening Br. at 48-51.) That is undoubtedly an appropriate argument under Rule 12(b)(6), and plaintiffs cannot seriously contend otherwise. Moreover, defendants' secondary arguments – that documents properly before the court (including some of the very same documents relied upon by plaintiffs) belie plaintiffs' scienter theory – also is proper under Rule 12(b)(6). *See Tellabs*, 127 S. Ct. at 2509 (discussing documents properly considered on motion to dismiss); *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) (same); *see also, e.g., In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 292 (S.D.N.Y. 2007) (on motion to dismiss, finding that plaintiffs' allegations regarding insider trading failed to plead scienter); *In re BISYS*, 397 F. Supp. 2d at 445 (same); *In re Keyspan*, 383 F. Supp. 2d at 386 (same).

They also misleadingly argue that GSK's meta-analysis reflected a "statistically significant link" between Avandia and the risk of heart attack, and, therefore, defendants were obliged to disclose that information whenever they spoke about Avandia (Pls.' Opp'n Br. at 15, 3). In fact, the meta-analysis results did ***not*** show a "statistically significant link between the use of Avandia and the risk of heart attack;" nor does the Complaint allege any such connection. (*See, e.g.,* Defs.' Opening Br. at 3 n.6, 16-18; Defs.' Exh. 15, von Eschenbach Statement at 9; Defs.' Exh. 16, FDA Adv. Comm. Brief at 1; Defs.' Exh. 17, FDA Adv. Comm. Intro. Mem. at 4; Defs.' Exh. 45, Results from GSK Meta-Analysis and Balanced Cohort Study.) Thus, plaintiffs' argument completely misconstrues *Carter-Wallace I* and its progeny and misstates facts pleaded in the Complaint and presented in public documents before the Court.

In *Carter-Wallace I*, the Second Circuit was not concerned with "statistical significance" in and of itself. Indeed, plaintiffs cull the words "statistical significant" from the decision bereft of any context. (Pls.' Opp'n Br. at 15.) The actual quotation from the decision makes clear that disclosure of safety data is required only where there is "statistically significant ***evidence*** that the ill effects may be ***caused by – rather than randomly associated with – use of the drugs and are sufficiently serious and frequent to affect future earnings***." *Carter-Wallace I*, 150 F.3d at 157 (emphasis added). In other words, under *Carter-Wallace I*, a securities fraud plaintiff must plead facts showing that a company had sufficiently reliable scientific data to put the company on notice that it can no longer reasonably have confidence in the product's future. Thus, statistical significance is not the critical inquiry; the critical inquiry is whether the available data is sufficiently reliable to rise to a level that would support a conclusion that there is a risk to future earnings.

The court's decision in *In re Bayer AG Securities Litigation*, No. 03-Civ-1546, 2004 WL 2190357 (S.D.N.Y. Sept. 30, 2003), which plaintiffs also misconstrue, confirms this interpretation of *Carter-Wallace I*. Plaintiffs suggest that the *Bayer* decision is inapplicable because it deals with "safety issues with the drug derived from 'adverse event reports.'" (Pls.' Opp'n Br. at 16.) In fact, as shown in defendants' Opening Brief, the plaintiffs in *Bayer* alleged numerous facts that were at least strongly suggestive of a safety issue with Baycol (in contradistinction to the dearth of facts pleaded here), including an internal study of adverse event reports by an epidemiologist suggesting that the safety risk for Baycol was five to 67 times greater than with other drugs. *Bayer*, 2004 WL 2190357 at *4. Yet, following the holding of *Carter-Wallace I*, the *Bayer* court found that positive statements regarding Baycol were not materially misleading ***until*** the company had sufficient reliable data to reach a "consensus" that the future of the brand was "at risk."[12] The Court specifically held that before an August 2000 meeting at which senior members of Bayer's management reached a consensus, including a

[12] Plaintiffs focus much of their argument on the unremarkable proposition that "once corporate officers undertake to make statements, they are obligated to speak truthfully and to make such additional disclosures as are necessary to avoid rendering the statements made misleading." (Pls.' Opp'n Br. at 12-13.) But this broad proposition is immaterial. The disclosure requirements applicable to this case are governed by *Carter-Wallace I*, which considered and rejected the notion that drug companies must disclose all safety information about a product anytime they discuss that product. *Carter-Wallace I*, 150 F.3d at 157 (plaintiffs claimed that defendants had a duty to disclose adverse event reports because it had "reported in its Form 10-K an increase in sales attributable to Felbatol, significant royalties from licensing the drug, and the expectation of increased Felbatol sales in the future."); *see also Bayer*, 2004 WL 2190357 at * 8 ("The Complaint asserts that defendants' pre-August 2001 statements regarding Baycol's safety profile and regulatory approval were rendered materially inaccurate by defendants' failure to disclose adequate information about the drug's health risks."); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000) ("Carter-*Wallace II*") (rejecting plaintiffs' attempt to distinguish *Carter Wallace I* on the grounds that plaintiffs were putting at issue "affirmative" statements, rather than a pure omission case). Furthermore, the broad, generalized statements regarding the future financial success are so attenuated from the specific results of the meta-analyses that failure to disclose the meta-analyses could not render those statements misleading as a matter of law. *See In re Praecis Pharm., Inc. Sec. Litig.*, No. 04-12581-GAO, 2007 WL 951695, at *7 (D. Mass. Mar. 28, 2007) (rejecting plaintiff's argument that statements in a press release were misleading on grounds that "[t]he release made no statements on [specific] topics that needed qualification as suggested by plaintiffs in order to avoid misleading a reader of the release."); *In re Ford Motor Co. Sec. Litig.*, 184 F. Supp. 2d 626, 632-33 (E.D. Mich. 2001) (finding no duty to disclose because the vague and general public statements had no connection to the omitted information).

consensus that the safety issues were sufficient to put the brand at risk, there was no duty to disclose any of the bits and pieces of earlier data – even though some of that data was arguably suggestive of a safety issue. *Id.* at **8-10.

The holdings of *Carter-Wallace I* and *Bayer* are grounded in important policy considerations that reflect a careful balancing of the benefits and risks associated with disclosing safety concerns about the use of medicine. As the FDA has explained: "[C]ommunication [of safety information] must be responsible and measured, taking into account the impact that the message will have on patients and practitioners alike, to encourage good health care choices, and help avoid bad ones." (Defs.' Exh. 15, von Eschenbach Statement at 4.) Pharmaceutical companies must therefore be cautious in disclosing data regarding a medicine's safety profile where the information's clinical significance is inconclusive or uncertain. Indeed, questioning the safety of a medicine publicly before reliable scientific data support a conclusion that the product actually presents safety risks could lead some patients to stop using the medicine, even though it might later be confirmed that the benefits of continued use far outweighed any risks for that patient. (*See* Defs.' Exh. 15, von Eschenbach Statement at 4-5 ("There are consequences in communicating safety concerns when FDA's safety assessment is still underway and before it has decided what, if any, regulatory action is appropriate. In light of a signal of concern in a diabetes drug like rosiglitazone, patients may choose to unilaterally discontinue their treatment, despite advice from FDA and other medical experts not to do so."). The rule of *Carter-Wallace* and *Bayer* attempts to reconcile these important concerns by requiring disclosure only where there is sufficiently reliable scientific evidence of a causal connection between a product and the alleged safety risks such that the future viability of the product is jeopardized.

Here, plaintiffs plead ***no facts*** in their Complaint showing that the meta-analyses satisfied these criteria, particularly in light of other available data. They just baldly state: "The AC alleges that Glaxo had conducted internal studies – the Meta-Analyses – which linked the use of Avandia to an increased risk of heart attack." (Pls.' Opp'n Br. at 16.) But, as both the FDA and Dr. Nissen have acknowledged, meta-analyses have serious limitations. (Defs.' Opening Br. at 3 n.7, 39.)[13] They are a tool to provide some information, but they are not structured to provide conclusive results in isolation. That is especially true when, as here, their results are inconsistent with the findings of a number of more rigorous clinical studies. Thus, plaintiffs' conclusory assertion is plainly insufficient under Rule 9(b) and the PSLRA. *See In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 40 (2d Cir. 2000) ("*Carter-Wallace II*") (plaintiffs' bare allegation that "the causal connection between Felbatol and aplastic anemia was made before August 1, 1994" was insufficient because "'conclusory allegations' do not satisfy the pleading requirements of Rule 9(b)").

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[13] Plaintiffs contend that it is "patently absurd" for defendants to claim that meta-analyses are not meaningful studies because defendants conducted them, urge that the reliability of meta-analyses is a factual issue and insist that the FDA Commissioner should not be believed because the "FDA has come under fire for failing to quickly respond to information concerning drug safety." (Pls.' Opp'n Br. at 15 n.19.) But the question is not whether meta-analyses can serve some meaningful purpose – they do, *i.e.*, identifying issues for potential further inquiry – but whether they are understood to be less reliable than other modes of analyses. Even Dr. Nissen acknowledges that they are. (*See* Defs.' Opening Br. at 39.) And it is plaintiffs' burden to plead ***facts*** that show with specificity why defendants had an obligation to disclose the meta-analyses. *Antigenics Inc. v. U.S. Bancorp Piper Jaffray, Inc.*, No. 03-Civ-0971 (RCC), 2004 WL 51224 at * 4 (S.D.N.Y. Jan. 9, 2004) (finding that claims of fraud by omission inadequately pleaded where "there is no statement of facts provided by the plaintiff that would support a 'reasonable belief as to the misleading nature of the statement or omission'") (citation omitted); *In re Merrill Lynch & Co., Inc. Research Reports Sec. Litig.*, 272 F. Supp.2d 243, 248 (S.D.N.Y. 2003) (dismissing claims where "[p]laintiff has failed to plead facts sufficient to show that the Defendants had a duty to disclose the information allegedly omitted from the Fund's Prospectuses and Registration Statements"). Here, the Complaint alleges ***no*** facts, much less particularized facts, explaining why the results of a meta-analysis, in and of itself, could "put the brand at risk," as required by *Carter-Wallace I* and *Carter-Wallace II*. Instead, as explained *supra* and in Defendants' Opening Brief, the Complaint makes allegations and refers to documents which support the opposite conclusion, *i.e.*, that the meta-analysis results could not be considered in isolation and, when compared to other available cardiovascular safety data, were inconsistent, uncertain and inconclusive.

Nor is this case remotely similar to the primary case on which plaintiffs rely, *In re Regeneron Pharmaceuticals Securities Litigation*, No. 94-Civ-1785, 1995 WL 228336 (S.D.N.Y. Mar. 10, 1995). *Regeneron* – which was decided before the Second Circuit's decision in *Carter Wallace I* (and the passage of the PSLRA) and therefore is ***not*** "particularly instructive," as plaintiffs claim (Pls.' Opp'n Br. at 13) – is a case in which a company allegedly mischaracterized the results of the very clinical trials it had run. The defendant in *Regeneron* had undertaken a three-phased clinical study of its product. After the end of the first two phases, the company asserted the drug "was safe and well tolerated" during a particular time period at all of the doses used in the Phase II trial. The plaintiffs alleged that this assertion was false because, according to the plaintiffs, the clinical trials themselves demonstrated that the drug was ***not*** well tolerated at the highest Phase II dose level – which was also the only level at which the drug appeared to be effective. *Regeneron*, 1995 WL 228336, at *4. Plaintiffs here have made no such allegations. To the contrary, plaintiffs' own allegations here show that even the FDA was uncertain about the clinical significance of GSK's meta-analysis in light of the conflicting data.[14]

Finally, the fact that at some later point GSK discussed the results of some clinical trials without disclosing the meta-analyses (Pls.' Opp'n Br. at 14) is of no moment. Clinical trials are categorically more reliable than meta-analyses. (Defs.' Opening Br. at 3 n.7, 39.) Indeed, the utility of a meta-analysis is that it can give rise to an inquiry that would cause a company to conduct more rigorous clinical trials. There is therefore nothing misleading about

[14] Similarly, neither the unpublished decision in *In re Forest Laboratories Securities Litigation*, attached as Exhibit G to plaintiffs' brief (which nowhere cites *Carter Wallace I*), nor any of the other cases cited by plaintiffs, *see, e.g., In re Neopharm, Inc. Sec. Litig.*, No. 02 C 2976, 2003 WL 262369 (N.D. Ill. Feb. 7, 2003), involved a situation where, as here, the plaintiff's own factual allegations showed that the clinical significance of the information at issue was inconclusive and uncertain. Indeed, the allegedly undisclosed data at issue in *Forest Laboratories* came, not from a meta-analysis, but from a large, six-year clinical study. (*See* Pls.' Exh. G at 11.)

disclosing the results of clinical trials without mentioning the results of less reliable meta-analyses.

In sum, even when given the benefit of all reasonable inferences from the facts alleged in their Complaint, plaintiffs' duty to disclose theory fails as a matter of law. Not only have plaintiffs failed to aver sufficient facts in support their claim that defendants had a duty to disclose GSK's meta-analysis results, but the facts they have alleged, and the documents referenced in the Complaint, completely undermine any such theory. This is yet another independent basis for dismissing the Complaint.

D. Plaintiffs' Claims Are Barred By The PSLRA's Safe Harbor Provision

Plaintiffs' Opposition Brief fails to present any viable argument as to why their claims based on GSK's forward-looking statements should be spared from dismissal as required by the PSLRA's safe harbor provision. First, plaintiffs make no effort to challenge defendants' identification of certain allegedly misleading statements as "forward-looking" (Defs.' Opening Br. at 57). While plaintiffs vaguely contend that some of the statements would not qualify as forward-looking statements if they included aspects of present or past fact, plaintiffs do not identify a single statement that falls within this category. (Pls. Opp'n Br. at 28.) Moreover, "mixed statements consisting of forward looking and non-forward looking factors are nonetheless treated by courts as forward looking." *See In re Merrill Lynch & Co. Sec. Litig.*, 273 F. Supp. 2d 351, 376 (S.D.N.Y. 2003) (citing *Harris v. Ivax Corp.*, 182 F.3d 799, 806-07 (11th Cir. 1999)).

Second, plaintiffs have failed to allege the "actual knowledge" necessary to remove GSK's forward-looking statements from the protection of the safe harbor. *In re Eastman Kodak Co.*, No. 6:05-CV-6326, 2006 WL 3149361, at *4 (W.D.N.Y. Nov. 1, 2006) ("An even

more stringent scienter requirement applies to forward-looking statements . . . where plaintiffs must plead facts to support the strong inference that the speaker had actual knowledge that the statement was false or misleading when made."). As discussed *supra* and in defendants' Opening Brief, plaintiffs' allegations fail to plead recklessness much less actual knowledge. Accordingly, ***all*** of plaintiffs claims based on GSK's forward-looking statements must be dismissed.

E. Plaintiffs' Request To Amend Should Be Denied

All of the facts that plaintiffs seek to allege in a new complaint are already before the Court, as plaintiffs have argued them in their Opposition Brief in an attempt to salvage their deficient allegations. The first and primary set of "new" allegations plaintiffs seek to add relate to the interactions between GSK and Dr. Buse, but, for the reasons discussed above, allegations regarding those interactions do not help plaintiffs state any claim for relief here. (*See supra* Section II.B.1.) Thus, there would be no point in granting plaintiffs leave to amend. Moreover, such allegations would aver no "new" facts. To the contrary, the facts regarding those interactions were fully and publicly discussed in a hearing before the U.S. House of Representatives' Committee on Oversight and Government Reform, chaired by Representative Henry A. Waxman (the "Waxman Hearing"), on June 6, 2007, ***before*** the original complaint was filed in this action on June 11, 2007, and the written statements and testimony from the Waxman Hearing were made publicly available on the Committee's website immediately following the hearing on June 6, 2007. (*See* http://oversight.house.gov/story.asp?ID=1325.) Indeed, the Institutional Investor Group ("IIG") referred to these same events involving Dr. Buse in a brief it filed in this case on September 7, 2007, ***over two months*** before plaintiffs filed their Amended Complaint. (*See* IIG's Reply Brief at 11-12 & n. 14.) Thus, plaintiffs had ample opportunity to include allegations pertaining to Dr. Buse's interactions with GSK in their Amended Complaint,

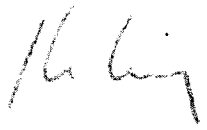
and they should not be permitted to further amend on the purported ground that such information is "new."

Plaintiffs also base their request for leave to amend on a recent meta-analysis, published in *The Journal of the American Medical Association* on December 12, 2007. (*See* Pls.' Opp'n Br. at 10-11, Pls.' Exh. C.) As explained in the December 11, 2007 *Reuters* article and the December 12, 2007 *The New York Times* article referenced in plaintiffs' Opposition Brief, the FDA issued a statement that this meta-analysis "does not change [the Agency's] recommendations [regarding Avandia]." (Pls.' Exh. E.) Moreover, the results of the meta-analysis were published long after the end of the putative Class Period and the filing of this action. They thus say nothing about the truth or falsity of any statements made during the Class Period, let alone about defendants' state of mind. Because their addition to the complaint would therefore be futile, leave to amend should be denied. *See Chill v. General Elec. Co.*, 101 F.3d 263, 271-72 (2d Cir. 1996); *In re Merrill Lynch & Co.*, 273 F. Supp. 2d 351, 393 (S.D.N.Y. 2003); *In re Cybershop.com Sec. Litig.*, 189 F. Supp. 2d 214, 236-37 (D.N.J. 2002).

III. CONCLUSION

For all of reasons set forth above and in their Opening Brief, defendants respectfully request that the Court dismiss plaintiffs' Amended Complaint in its entirety and with prejudice.

Respectfully submitted:



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